3/12/99

510(k) Summary

K984580

Safety and effectiveness information concerning the Biosaca from Biosys AB is summarized below.

Date Prepared December 18, 1998

Applicant

BIOSYS AB (publ)
Vasaplatsen 8
SE-411 34 Göteborg
Telephone: +46 31 774 21 25
Fax: +46 31 13 98 54
e-mail: info@biosys.se

Contact Anne Mari Nedevska, Technical Administration Manager

Device Name BIOSACA

Common Name Biological Signal Recorder

Classification No formal classification name or number has been assigned for devices such as the Biosaca. Stand-alone devices for the same use as the Biosaca include the following:

Panel	Product Code	Name	21 CFR
84	GWQ	Electroencephalograph	882.1400
84	GYE	Physiological telemetry system	882.1855
84	GWP	Electromyography	882.5050
84	LEL	Sleep Assessment Device	
80	FLS	Breathing frequency	868.2375
73	MNR	Ventilatory effort recorder	868.2375
74	DPS	Electrocardiography (ECG)	870.2340
74	DQA	Pulse Oximeter	870.2700
73	DRX	Electrocardiograph electrode	870.2360

Submission Correspondent

Jane B. Campbell
J. & D. Campbell Associates, Inc.
485 LaRoe Road
Chester, New York 10918
Tel. 914-469-4289
Fax. 914-469-4212
e-mail: jdca@warwick.net

Predicate Devices Compumedics Sleep Monitoring System, Compumedics Sleep Pty. Ltd (K955841)

Embla, Flaga hf. (K971813)

Device Description The BIOSACA is a multi-functional and an ambulatory recording device. It is a portable system for the recording, monitoring, storage and transfer of up to 22 bioparameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing, body movements etc. There are applications for the BIOSACA in neurological, cardiology and sleep disorder diagnoses.

Function The BIOSACA is a biological signal recorder able to receive and record up to 22 bioparameters - 16 from two headboxes, AC and/or DC, three from the pulse oximeter and three from the sensor pad.

Intended Use The intended use for the BIOSACA is to record, monitor, display, print, store and transfer bioparameters such as brain, heart and muscle activity, eye movement, blood pressure, breathing and body movements.

The BIOSACA unit is intended to be used on an Adult population and for use at home or in health care facilities. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units. The unit may be used for electrocardiography, electroencephalography, electromyography, electrooculography ballistocardiography and with AC and DC sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 1999

Biosys AB
c/o Jane B.Campbell
J. D. Campbell Associates
485 Laroe Road
Chester, New York 10918

Re: K984580
Trade Name: BIOSACA
Regulatory Class: II
Product Code: GWQ, GWL, or MNR
Dated: December 18, 1998
Received: December 23, 1998

Dear Ms. Campbell:

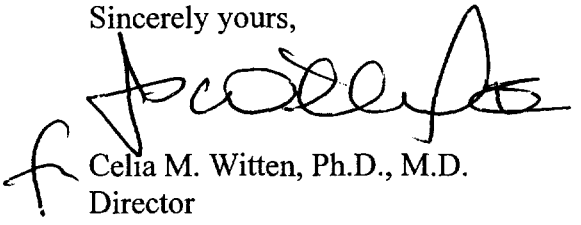
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K984580

Device Name: BIOSACA

Indications for Use:

The BIOSACA equipment is indicated for use in the recording, displaying, monitoring, printing and storage of biological and non-biological signals for sleep disorder and epilepsy investigations as well as Electroencephalography (EEG), Electrocardiography (ECG), Electromyography (EMG), Electrooculography (EOG), Ballistocardiography, etc. BIOSACA is designed for both stationary and mobile operation and may be used in either the patient's home or the hospital. Biological signals are electrical signals which can be recorded directly from the patient. Non-biological signals are recorded using indirect methods such as recording the flow of air (breathing), blood pressure, etc.

The equipment is suitable for home use as the patient needs only a minimal amount of instruction in how to use it. The system has no lights or sounds that could confuse the patient. Signals may be stored for later or may be viewed directly in real-time in the hospital, for instance. When monitoring, the operator sees the signals at the same time as they are recorded.

The Biosaca unit is intended for use on an adult population and at home or in health care facilities. It is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984580

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)